

**Michigan Disease Surveillance System Syndromic Surveillance Module
Data Use and Confidentiality Agreement
Between
The Michigan Department of Community Health
And
_____ Health System**

The Michigan Department of Community Health (MDCH) and _____ (the Health System) enter into this Data Use and Confidentiality Agreement (the Agreement) effective ____ / ____ / ____ (“Effective Date”). The Health System and MDCH shall be referred to individually as a “Party” or collectively as the “Parties”.

RECITALS

WHEREAS:

- A. MDCH is a Public Health Authority that is authorized by the Public Health Code to collect or receive protected health information for the purpose of preventing or controlling disease, injury, or disability, and conduct public health surveillance, public health investigations, and public health interventions. MCL 333.2221, 45 CFR §164.512(b)(1)(i).
- B. The Health System is a health care provider that meets requirements established by MDCH to participate in the Michigan Disease Surveillance System Syndromic Surveillance Project (the Project).
- C. As a Public Health Authority, MDCH has developed the Michigan Disease Surveillance System Syndromic Surveillance Module (the Module)
- D. The Module is a public health surveillance system that uses components of the Real-time Outbreak Detection System (RODS) developed by the Center for Biomedical Informatics of the University of Pittsburgh.
- E. The Module is designed to enable public health officials to rapidly detect and track the unusual outbreaks of illness that may be the result of bioterrorism, other outbreaks of infectious disease or other public health threats and emergencies
- F. The Module is capable of collecting data relevant to public health automatically and in real time; it is intended to be and will be used by public health officials by providing tools for the display and analysis of the data.
- G. Real time detection of a notable increase in patients presenting for care with symptoms suggestive of intentional release of a biological agent will facilitate

early detection and intervention, thereby saving lives and mitigating the extent of disruption to normal daily activities.

- H. Modules that analyze frequency of symptoms over time offer early detection thereby avoiding delays of several days associated with normal disease reporting process.
- I. Such modules are becoming increasingly important given the emerging threat of bioterrorism. This urgent need has been highlighted in a recent report from the Institute of Medicine Microbial Threats to Health: Emergence, Detection & Response (2003).
- J. The Module will also assist state and local health departments in establishing expanded epidemiologic capacity to investigate and mitigate such outbreaks of illness.
- K. The Module provides tools that include automatic data collection, automatic aberration detection algorithms and tools that support temporal and spatial data analysis and visualization. If the Module detects a significant increase it will trigger an automated notice to MDCH epidemiologists who in turn can analyze findings, investigate further and contact local Public Health agencies and provider entities when warranted.
- L. The Module is designed to fulfill the Syndromic Surveillance component of cooperative agreements administered by the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188.
- M. Pursuant to such cooperative agreements, CDC and HRSA have provided funding to the State of Michigan and cooperating health systems to enhance preparations against terrorism and other public health emergencies and further the objectives of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.
- N. The Health System and MDCH are implementing the Project utilizing RODS and other surveillance techniques.
- O. The Health System will be providing data for analysis for the Project.
- P. The Health System data, as defined below, and analysis information will be available to MDCH for public health surveillance purposes only. MDCH and appropriate Local Health Departments will be able to review aggregate time-trended and spatially displayed data.

Q. Oversight of the project will be provided by a board comprising representatives of the State of Michigan, participating health systems, and Local Health Departments, (the Steering Committee).

R. The parties shall abide by all applicable federal and state laws, rules and regulations, including without limitation all patient confidentiality and medical records requirements, and any applicable IRB requirements.

NOW, THEREFORE, in consideration of the mutual covenants set forth herein, and intending to be legally bound hereby, the parties agree as follows:

1. Definitions.

a) "HIPAA Privacy Rule" means regulations adopted by the United States Department of Health and Human Services pursuant to the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, which establishes national standards for the use and disclosure of health information. The HIPAA Privacy Rule is set out at 45 CFR Parts 160 and 164.

b) "Health System Data", for purposes of this agreement is:

Protected health information that has all direct identifiers removed so that it meets the criteria of a "limited data set", as set out in the HIPAA Privacy Rule, 45 CFR §164.514(e)(2), that the Health System elects to release to the Project. The Parties anticipate that the Health System Data may include the following types of information:

i) An abstract of each visit comprising time of visit, entity identifier, patient class, patient date of birth, gender, chief complaint, local ZIP code and a sequential transmission number;

ii) Such other data that has direct identifiers removed as the Health System may in its sole discretion elect to release to the Project.

c) "Confidential Information" shall consist of: (1) all the Health System Data, and (2) all other written or orally disclosed information or electronically exchanged information of any Party provided to any other Party, directly or indirectly, pursuant to the Project which is clearly designated in writing as "Confidential", or in the case of oral disclosure, is identified in writing as "Confidential" within ten days, with the exception of any information that:

i) was in the recipient Party's lawful possession prior to disclosure by the owner Party; or

ii) is lawfully received by a Party without restriction regarding use or confidentiality from an independent third party who is in lawful possession of said information; or

iii) is now or hereafter becomes generally available to the public through no action, inaction, or fault of any Party hereto.

d. "Steering Committee" means the committee described within Paragraph Q of the recitals.

2. Provision of the Health System Data.

The Health System shall provide the Health System Data to MDCH for use in connection with the public health surveillance functions of the Project. The Health System shall transmit the data electronically and in real time to the extent practical. All the Health System Data shall at all times remain the property of the Health System and shall be returned to the Health System in its original form, and any aggregated or derivative form, immediately upon request.

3. Management of Data.

The Health System Data will be received and stored in a computer located in a machine room maintained by MDCH, and/or the Michigan Department of Information Technology (DIT), serving as MDCH's agent. MDCH and its agent, DIT shall use all reasonable administrative, physical and technical safeguards (based on industry best practices) to secure, protect and manage the Health System Data in compliance with the terms of this Agreement. DIT may designate a data transfer agent to provide virtual private network (VPN) services between the Health System and DIT.

Throughout the term of this Agreement, MDCH shall make the Health System data and all aggregated data provided by other participants in the Project, including data summaries and analysis produced by the Project, available to designated personnel of MDCH and Local Health Departments, as required in order to carry out the public health surveillance functions of the Project.

Participants in the project will receive regular updates on the status of the surveillance project. Further, a Steering Committee will determine the most appropriate presentation of data for participants.

To the extent MDCH requests a Health System to disclose protected health information and limited data sets, such requests will only be for the minimum data necessary to accomplish the authorized purpose of the request.

4. Confidentiality of Information.

a) Each Party and its agents shall hold all Confidential Information of the other Parties in strict confidence and shall not disclose any Confidential Information to any person or entity except as authorized by this Agreement or as required by law or by court order.

b) Each Party shall use the Confidential Information of the other Parties only for the purpose of performing the public health surveillance functions of the Project and for no other purpose whatsoever. No party shall release any Confidential Information of any other party without the express written consent of the other Parties, or without notice to the other Parties, where release is required by law or by court order.

c) Each Party shall strictly limit access to the relevant portions of the Confidential Information of the other Parties to such of its employees as delineated herein who have a need to know such portions of the Confidential Information regarding the Project.

d) Confidentiality and security of information shared pursuant to this agreement is essential to ensure the privacy of patient health information and to protect the national security and the health, safety, and welfare of the public.

e) No Party shall make copies of any Confidential Information of the other Parties, except for its internal use regarding the Project, or as required by law or by court order.

f) Each Party shall return or destroy all originals and copies of the Confidential Information (and derivatives thereof) immediately upon request of an owner Party.

g) The Health System, as a "covered entity" under the HIPAA Privacy Rule, is authorized to release a limited data set to MDCH, without individual patients' authorization, for research or public health purposes, subject to assurances of confidentiality, as provided by the Privacy Rule. 45 CFR §§164.514(e)(3)(i), 164.514(e)(4), 164.512(b)(1)(i).

h) The nonuse and confidentiality limitations and all other restrictions set forth herein shall be binding upon the subsidiary and affiliated entities, agents and subcontractors of the Parties hereto. Each Party hereto shall take such necessary actions to ensure the compliance herewith by any such subsidiary and affiliated entities, agents and subcontractors.

i) Consistent with subsections a) and b) herein, MDCH shall exercise its discretion to exempt from public disclosure the Health System Data, which is provided voluntarily by the Health System pursuant to this Agreement, as permitted under section 13(1) of under the Michigan Freedom of Information Act

(FOIA) MCL 15.231 et seq., and shall notify the Health System should it receive any FOIA request for such Health System Data.

j) MDCH, Steering Committee and Health Systems shall within 15 days of becoming aware of any use or disclosure of protected health information or limited data set in violation of this Agreement by any of its officers, directors, employees, subcontractors or agents or by a third party, report such violation to the Health System which owns the data.

k) MDCH shall use appropriate safeguards to prevent use or disclosure of the Health System Data inconsistent with this Agreement.

l) MDCH shall report to the Health System any use or disclosure of the Health System Data not provided for by this Agreement of which it becomes aware.

m) MDCH shall not identify the Health System Data or contact the individuals whose information is part of the Health System Data.

5. Governance.

a) The Project will be maintained by a board comprised of representatives of the State of Michigan, participating Health Systems, and Local Health Departments, (the "Steering Committee"); and

b) The Steering Committee shall be responsible for oversight of the Project.

6. Institutional Review Board ("IRB") Approvals.

As relevant and appropriate, the Parties shall abide by all applicable IRB requirements and/or requirements of the Health System Information Security Committee ("ISC"). Where IRB or ISC oversight is required, the Parties shall provide such documentation of compliance to each other.

7. The Health System's Disclaimer of Warranties.

EXCEPT AS SET FORTH IN THIS AGREEMENT, THE HEALTH SYSTEM DISCLAIMS ALL WARRANTIES WHETHER WRITTEN, ORAL, EXPRESSED OR IMPLIED INCLUDING, WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, ANY WARRANTY OF DATA ACCURACY, COMPLETENESS, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

8. MDCH's Disclaimer of Warranties.

MDCH DISCLAIMS ALL WARRANTIES WITH RESPECT TO THE PROJECT, WHETHER WRITTEN, ORAL, EXPRESSED OR IMPLIED INCLUDING, WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, ANY WARRANTY OF DATA ACCURACY, COMPLETENESS, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

9. As stated in the University of Pittsburgh's Disclaimer of Warranties:

UNIVERSITY OF PITTSBURGH DISCLAIMS ALL WARRANTIES WITH RESPECT TO RODS, WHETHER WRITTEN, ORAL, EXPRESSED OR IMPLIED INCLUDING, WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, ANY WARRANTY OF DATA ACCURACY, COMPLETENESS, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

10. Regulatory Compliance. MDCH shall take such actions as are necessary, including making modifications of the Health System Data, to comply with all applicable Health System policies and procedures, and all applicable federal, state or local statutes or regulations (whether promulgated before or after the date the Health System Data was received), including without limitation, all applicable requirements of the HIPAA Privacy Rule. MDCH shall perform such work at its own expense. Such actions will be completed within the times specified for compliance within the statute or regulation. The Health System shall have the right at all times to review and inspect the steps taken and procedures implemented by the State of Michigan to assure that patient data has no links to direct identifiers and the compliance with all such requirements and the terms of this Agreement.

11. Audits & Compliance. The Health System, at the Health System's expense, shall be permitted to perform reasonable audits to ensure that appropriate controls have been established so that data management and use is consistent with the terms of this Agreement. Based on such audits the Health System may require MDCH to modify the Health System Data and controls to comply with any of the Health System's requested changes. MDCH may, at its discretion, return the Health System Data to the Health System in its original form and any aggregated or derivative form, and terminate this agreement per Paragraph 12 if compliance with required modifications in the Health System Data and controls cannot be achieved without undue burden as determined by MDCH.

12. Term and Termination. The term of this Agreement shall be for a period of three (3) years from the effective date hereof. Either party may terminate this agreement without cause immediately upon notice to the other party. In such event, Paragraphs 4, 6, 7, 8 and 9 shall survive the termination of the Agreement.

13. Miscellaneous

- a) The terms and conditions of this Agreement supercede all previous oral or written representations, understandings or agreements not incorporated into this Agreement.
- b) This Agreement shall not be amended or modified, unless approved in writing by the Parties.
- c) If any provision of this Agreement shall be held illegal or unenforceable by a court having jurisdiction, such provision shall be modified to the extent necessary to render it enforceable by a court having jurisdiction, such provision shall be modified to the extent necessary to render it enforceable without losing its intent, or severed from this Agreement if no such modification is possible, and other provisions of this Agreement shall remain in full force and effect.
- d) The relationship between MDCH, and Health Systems is that of independent contractors and neither Party nor its agents shall have any authority to bind the other Party in any way.
- e) Nothing express or implied in this Agreement is intended to confer, nor shall anything in this Agreement confer upon any person, other than MDCH and Health Systems and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.

Jean C. Chabut, Chief Administrative Officer
Public Health Administration

Date

Signature, Health System

Date

Printed Name, Health System